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UTILITY PATENT APPLICATION TRANSMITTAL

Attorney Docket No.	7922	Total Pages	27
First name inventor or Application Identifier			
Gary (NMN) Stephenson			
Express Mail Label No.			
EE841941813US			

(Only for new nonprovisional applications under 37 CFR 1.53(b))

APPLICATION ELEMENTS

See MPEP Chapter 600 concerning utility patent application contents.

 ADDRESS TO: Assistant Commissioner for Patents
 Box Patent Application
 Washington, D.C. 20231

1. ☒ Fee Transmittal Form
(Submit an original, and a duplicate for fee processing)
2. ☒ Specification Total Pages [27]
(preferred arrangement set forth below)
- Descriptive Title of the Invention
 - Cross References to Related Applications
 - Statement Regarding Fed sponsored R&D
 - Reference to Microfiche Application
 - Background of the Invention
 - Brief summary of the Invention
 - Brief Description of the Drawings *(if filed)*
 - Detailed Description
 - Claim(s)
 - Abstract of the Disclosure
- ☐ Drawing(s) (35 USC 113) Total Sheets ☐
4. Oath or Declaration
- a. ☒ Newly executed (original or copy)
- b. ☐ Copy from a prior application (37 CFR 1.63(d))
(for continuation/divisional with Box 17 completed)
[Note Box 5 below]
- i. ☐ DELETION OF INVENTORS
 Signed statement attached deleting
 inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.93(b).

6. ☐ Microfiche Computer Program (Appendix)
7. Nucleotide and/or Amino Acid Sequence Submission
(if applicable, all necessary)
- a. ☐ Computer Readable copy
 - b. ☐ Paper Copy *(identical to computer copy)*
 - c. ☐ Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

8. ☐ Assignment Papers (cover sheet & document(s))
9. ☐ 37 CFR 3.73(b) Statement ☐ Power of Attorney
(when there is an assignee)
10. ☐ English Translation Document *(if applicable)*
11. ☐ Information Disclosure ☐ Copies of IDS
 Statement (IDS)/PTO-1449 Citations
12. ☐ Preliminary Amendment
13. ☒ Return Receipt Postcard (MPEP 503)
(Should be specifically itemized)
14. ☐ Small Entity ☐ Statement filed in prior application
 Statement(s) Status still proper and desired
15. ☐ Certified Copy of Priority Document(s)
(if foreign priority is claimed)
16. ☐ Other:

5. ☐ Incorporation By Reference *(useable if Box 4b is checked)*
 The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

17. If a CONTINUING APPLICATION, check appropriate box and supply the requisite information:

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No. /

18. CORRESPONDENCE ADDRESS

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FEE TRANSMITTAL FORM

CLAIMS	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULATIONS
TOTAL CLAIMS (37 CFR 1.16 (c))		20 - 20	0	x \$18.00 =	\$0
INDEPENDENT CLAIMS (37 CFR 1.16 (c))		2 - 3	0	x \$78.00 =	\$0
MULTIPLE DEPENDENT CLAIMS (if applicable) (37 CFR 1.16(d))				+ \$260.00 =	\$0
				BASIC FEE (37 CFR 1.16(a))	\$690.00
				Total of above Calculations =	\$690.00
Reduction by 50% for filing by small entity (Note 37 CFR 1.9, 1.27, 1.28).					
TOTAL =					\$690.00

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22. SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

NAME	Kelly L. McDow-Dunham
SIGNATURE	<i>Kelly L. McDow-Dunham</i>
DATE	January 21, 2000

"Express Mail" mailing label number EFS41941813US

Date of Deposit January 21, 2000

I hereby certify that this paperfile is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Assistant Commissioner for Patents, Washington, D.C. 20531

Kelly L. McDow-Dunham 43,787
Attorney/Agent mailing application Reg No.

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Kelly L. McDow-Dunham 43,787
Attorney/Agent mailing application Reg. No.

Kelly L. McDow-Dunham
Signature of Attorney/Agent mailing application

P&G Case 7922

METHODS OF USING A BEVERAGE COMPOSITION

Gary (NMN) Stephenson

FIELD OF THE INVENTION

The present invention is directed to methods of treating dental erosion comprising orally administering a beverage composition to a mammal, preferably a human. The present invention is further directed to kits comprising the beverage compositions.

BACKGROUND OF THE INVENTION

Beverage compositions, for example, soft drink beverages (e.g., cola beverages) and fruit juice beverages, have the potential to cause the consumer of the beverage to experience dental erosion. Such dental erosion can result wherein the beverage composition is acidic in nature, i.e., exhibits a pH of about 5 or below. Additionally, since children are particularly susceptible to dental erosion relative to adults due to the smaller enamel surface to volume ratio, consumption of such beverages may be of particular concern for this group. Accordingly, since many consumers ingest acidic beverage compositions weekly, daily, or even more frequently, it would be advantageous to discover a beverage composition which protects against dental erosion.

The art suggests that such factors as pH, fluoride, calcium, and even phosphate concentration may have an effect on dental erosion and / or dental caries. For example, acidic pH, particularly about 5 or below, is typically considered to exacerbate dental erosion (which occurs by direct action of acid on the enamel surface). For example, Lussi et al., "Prediction of the Erosive Potential of Some Beverages", *Caries Research*, Vol. 29, pp. 349 - 354 (1995) examined the erosive potential of many beverage compositions, all having a pH of less than 5.

Furthermore, Borggreven et al., "The Influence of Various Amphiphilic Phosphates on *in vitro* Caries Lesion Formation in Human Dental Enamel", *Caries Research*, Vol. 26, pp. 84 - 88 (1992) suggests enamel softening in the presence of certain polyphosphates at levels below pH 5.5. See Borggreven et al., p. 87.

The art suggests that further factors are important in dental erosion and / or dental caries. Lussi et al. (citation herein above) suggests that fluoride concentration is a further factor contributing to dental erosion. For example, among beverage compositions tested by Lussi et al., the compositions having the highest fluoride concentrations showed the smallest amount of surface softening of the enamel. However, highest phosphate concentrations did not necessarily correlate with decreased surface softening of the enamel. For example, apple juice, having a moderately high phosphate concentration relative to many other beverage compositions tested, was also the most erosive beverage composition tested. See Lussi et al., pp. 352 - 353.

There has been further experimentation with certain phosphates, including pyrophosphates and polyphosphates, with respect to dental health, particularly in the area of dental caries. For example, Städler et al., "The Effect of Sodium Trimetaphosphate on Caries: A 3-Year Clinical Toothpaste Trial", *Caries Research*, Vol. 30, pp. 418 - 422 (1996), suggests that trimetaphosphate (a cyclic phosphate) may be effective against dental caries. However, Städler et al. utilized toothpaste formulations having near-neutral pH rather than a more acidic formulation. Other studies have suggested efficacy against dental caries using certain phosphates, including polyphosphates, but such studies were typically conducted using formations having near-neutral pH. See e.g., McGaughey et al., "Effects of Polyphosphates on the Solubility and Mineralization of HA: Relevance to a Rationale for Anticaries Activity", *Journal of Dental Research*, pp. 579 - 587, June 1977 and Shibata et al., "Antibacterial Action of Condensed Phosphates on the Bacterium *Streptococcus Mutans* and Experimental Caries in the Hamster", *Archives of Oral Biology*, Vol. 27, pp. 809 - 816 (1982).

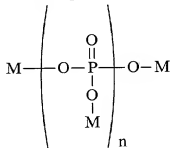
Another study did suggest the efficacy of monocalcium phosphate in low pH powdered beverage compositions for preventing molar erosion. See Reussner et al., "Effects of Phosphates in Acid-Containing Beverages on Tooth Erosion", *Journal of Dental Research*, pp. 365 - 370, March - April 1975. However, this same study further suggested that beverage compositions supplemented with other phosphates, including sodium hexametaphosphate, did not produce significant protective effects against molar erosion. See Reussner et al., p. 367.

Accordingly, there is a continuing need to discover a low pH beverage composition which is effective against dental erosion. In view of the art, the present inventor has surprisingly discovered that low pH beverage compositions comprising certain polyphosphates, as described more particularly herein, are effective against dental erosion. The present inventor has even further discovered that such efficacy may be in excess to similar compositions having such polyphosphate

replaced with calcium, which is known to be beneficial to the health of bones and teeth. The present inventor therefore describes herein methods of treating dental erosion using the defined beverage compositions and kits comprising the beverage compositions.

SUMMARY OF THE INVENTION

The present invention is directed to a method of treating dental erosion comprising orally administering to a mammal (preferably, a human) a beverage composition having a pH of less than about 5; wherein the beverage composition comprises a compound having the structure:



wherein n is an integer averaging from about 7 to about 100 and M, M', and M'' are each, independently, selected from the group consisting of sodium and potassium.

The present invention is further directed to kits comprising the foregoing beverage composition and information that use of the beverage composition provides treatment against dental erosion.

The methods and kits of the present invention are described more particularly herein below.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is directed to methods of treating dental erosion comprising orally administering a beverage composition to a mammal, preferably a human. The present invention is further directed to kits comprising the beverage compositions and information that use of the beverage composition provides treatment against dental erosion.

Publications and patents are referred to throughout this disclosure. All references cited herein are hereby incorporated by reference.

All percentages and ratios are calculated by weight unless otherwise indicated. All percentages and ratios are calculated based on the total composition unless otherwise indicated.

All component or composition levels are in reference to the active level of that component or composition, and are exclusive of impurities, for example, residual solvents or by-products, which may be present in commercially available sources.

Referred to herein are trade names for components including, but not limited to, certain carbohydrates, flavors, and other components. The inventor herein does not intend to be limited by materials under a certain trade name. Equivalent materials (e.g., those obtained from a different

source under a different name or catalog (reference) number) to those referenced by trade name may be substituted and utilized in the compositions, kits, and methods herein.

In the description of the invention various embodiments and/or individual features are disclosed. As will be apparent to the ordinarily skilled practitioner, all combinations of such
 5 embodiments and features are possible and can result in preferred executions of the present invention.

The compositions, methods, and kits herein may comprise, consist essentially of, or consist of any of the elements as described herein.

Definitions

As used herein, the term "dental erosion" is defined as loss, softening, and / or
 10 demineralization of mammalian tooth substance (*i.e.*, demineralization of enamel of the tooth typically with dissolution of such enamel). Preferably, such loss of tooth substance occurs by direct action of acid on the tooth substance. Such acid may be, for example, present in the oral cavity either naturally, through chronic regurgitation (through conditions such as, for example, anorexia nervosa,
 15 bulimia nervosa, and / or gastrointestinal disturbances) and / or through administration of acidic (*i.e.*, having a pH of less than about 5) foods, beverages, pharmaceutical preparations (including over-the-counter and R_x), and / or nutraceutical preparations. See e.g., Lussi et al., "Prediction of the Erosive Potential of Some Beverages", *Caries Research*, Vol. 29, pp. 349 - 354 (1995). Preferably, such chemical processes are not directly related to the action of bacteria (*i.e.*, caries), which more typically
 20 results in cavity formation. Dental erosion may result in the aforementioned loss or softening of enamel and demineralization.

As used herein, the term "treating" with reference to the term "dental erosion" is defined as inhibiting (either partially or completely), reversing, and / or protecting against dental erosion with respect to the user of the present beverage composition. Most preferably, the term "treating" with
 25 reference to the term "dental erosion" is defined as inhibiting (either partially or completely) and / or protecting against dental erosion with respect to the user of the present beverage composition. Wherein dental erosion is "treated", conditions such as, for example, softening of enamel, demineralization, and / or cavity formation may be inhibited, reversed, and / or protected against.

Methods of the Present Invention

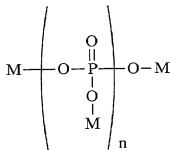
The present methods are directed to treating dental erosion comprising orally administering
 30 to a mammal a beverage composition having a pH of less than about 5, wherein the beverage composition comprises a polyphosphate compound having the defined structure set forth herein. Surprisingly, the present inventor has discovered that, despite the low pH of the beverage
 35 compositions, the present beverage compositions provide treatment against dental erosion. The

inventor herein has further excitingly discovered that such treatment is provided even wherein the beverage composition is substantially free of components which are often associated with treatment of dental erosion, *i.e.*, fluoride and / or calcium. The present inventor has further discovered that such treatment is also provided even wherein the beverage composition is substantially free of phosphate derived from one or more compounds other than the polyphosphate compound defined herein.

In accordance with the methods of the present invention, dental erosion is treated through orally administering to a mammal, preferably a human, a beverage composition having a pH of less than about 5 and comprising the polyphosphate compound as specifically defined herein. As used herein, the term "orally administering" with respect to the mammal (preferably, human) means that the mammal ingests or is directed to ingest (preferably, for the purpose of treatment against dental erosion) one or more beverage compositions of the present invention. Wherein the mammal is directed to ingest one or more of the beverage compositions, such direction may be that which instructs and / or informs the user that use of the beverage composition may and / or will provide treatment against dental erosion. For example, such direction may be oral direction (*e.g.*, through oral instruction from, for example, a physician, dental professional, sales professional or organization, and / or radio or television media (*i.e.*, advertisement) or written direction (*e.g.*, through written direction from, for example, a physician or dental professional (*e.g.*, scripts), sales professional or organization (*e.g.*, through, for example, marketing brochures, pamphlets, or other instructive paraphernalia), written media (*e.g.*, internet, electronic mail, or other computer-related media), and / or packaging associated with the beverage composition (*e.g.*, a label present on a package containing the beverage composition). As used herein, "written" means through words, pictures, symbols, and / or other visible descriptors. Such descriptors need not utilize the actual words "dental" and / or "erosion", but rather use of words, pictures, symbols, and the like conveying the same or similar meaning are contemplated within the scope of this invention.

According to the present invention, the mammal ingests or is directed to ingest one or more of the compositions as described herein. Such ingestion or direction is typically at least once monthly, more typically at least once weekly, and most preferably at least once daily. Preferably, such ingestion or direction is in place of erosive beverage compositions, for example, low pH beverage compositions or carbonated beverages which do not comprise a polyphosphate compound as described herein. Additionally, optimum treatment against dental health problems will typically further involve standard dental care, including using standard dentifrices according to standard methods, *e.g.*, using toothpastes and / or oral rinses which are intended for prophylaxis of common dental problems such as dental caries and the like.

As stated, the present method relates to treating dental erosion comprising orally administering to a mammal (preferably, a human) a beverage composition having a pH of less than about 5; wherein the beverage composition comprises a polyphosphate compound having the structure:



wherein n is an integer averaging from about 7 to about 100 and M , M' , and M'' are each, independently, selected from the group consisting of sodium and potassium.

Preferably, the present beverage compositions comprise from about 0.001% to about 0.5%, more preferably from about 0.03% to about 0.3%, even more preferably from about 0.05% to about 0.2%, and most preferably from about 0.05% to about 0.1% of the compound, by weight of the beverage composition.

Also preferably, n is an integer averaging from about 10 to about 30, more preferably averaging from about 13 to about 25, and most preferably averaging from about 19 to about 25. Most preferably, n is an integer averaging about 21.

Also preferably, each of M , M' , and M'' are sodium.

The present beverage compositions herein have a pH of less than about 5, preferably from about 2 to about 4.5, and most preferably from about 2.7 to about 3.5. Beverage composition acidity can be adjusted to and maintained within the requisite range by known and conventional methods, *e.g.*, the use of food grade acidulants and / or buffers. The component utilized to adjust and maintain the appropriate pH is not critical to the present invention. However, as non-limiting examples, organic as well as inorganic edible acids may be used to adjust the pH of the beverage composition. The acids may be present in their non-dissociated form or, alternatively, as their respective salts; for example, potassium or sodium hydrogen phosphate or potassium or sodium dihydrogen phosphate salts. The preferred acids are edible organic acids. The more preferred acids include citric acid, malic acid, fumaric acid, adipic acid, phosphoric acid, gluconic acid, tartaric acid, ascorbic acid, acetic acid, phosphoric acid, and mixtures thereof. The most preferred acids are citric and malic acids.

It has been further excitingly discovered that treatment of dental erosion is provided herein through use of the beverage composition even wherein the beverage composition is substantially free of components which are often associated with treatment of dental erosion, *i.e.*, fluoride and / or calcium. The present inventor has further discovered that such treatment is also provided even

wherein the beverage composition is substantially free of phosphate derived from compounds other than the polyphosphate compound defined herein. Accordingly, a preferred but not requisite embodiment herein are beverage compositions which are substantially free of fluoride, calcium, and / or phosphate derived from one or more compounds other than the polyphosphate compound defined herein. As used herein, "substantially free of fluoride" or the like means that the composition comprises less than about 0.1% of fluoride (as an element, including in ionic form), preferably less than about 0.075% of fluoride, more preferably less than about 0.05% of fluoride, and most preferably less than about 0.025% of fluoride, all by weight of the beverage composition. As used herein, "substantially free of calcium" or the like means that the composition comprises less than about 0.1% of calcium (as an element, including in ionic form), preferably less than about 0.075% of calcium, more preferably less than about 0.05% of calcium, and most preferably less than about 0.025% of calcium, all by weight of the beverage composition. As used herein, "substantially free of a phosphate derived from one or more compounds other than the polyphosphate compound defined herein" or the like means that the composition comprises less than about 0.1% of such other phosphate (as an element, including in ionic form), preferably less than about 0.075% of such other phosphate, more preferably less than about 0.05% of such other phosphate, and most preferably less than about 0.025% of such other phosphate, all by weight of the beverage composition.

In accordance with the present method it is further surprising that one or more sweeteners may be included in the beverage compositions with maintenance of treatment of dental erosion. Such sweeteners are described herein below as an optional component of the beverage composition.

Kits of the Present Invention

The present invention further relates to kits comprising a beverage composition as described herein and information that use of the beverage composition provides treatment against dental erosion. For example, such information may be oral information disseminated as part of the kit, but is preferably written information, typically present on packaging associated with the beverage composition (*e.g.*, a label present on a package containing the beverage composition or package insert included within the kit). As used herein, "written" means through words, pictures, symbols, and / or other visible information. Such information need not utilize the actual words "dental" and / or "erosion", but rather use of words, pictures, symbols, and the like conveying the same or similar meaning are contemplated within the scope of this invention. Such information may also include information about general dental health and reasons for which dental health, and particularly treatment against dental erosion, is important for the user.

Optional Components of the Beverage Compositions Utilized in the Present Kits and Methods

The compositions utilized in the kits and methods of the present invention may comprise additional optional components to enhance, for example, their stability, organoleptic properties and /
 5 or nutritional profile. For example, water, beverage emulsions, thickeners, sweeteners, coloring agents, nutrients, carbonation components, soluble fibers, preservatives, and the like may be included in the compositions herein. Such optional components may be dispersed, solubilized, or otherwise mixed into the present compositions. These components may be added to the compositions herein provided they do not substantially hinder the properties of the beverage composition. Non-limiting
 10 examples of optional components suitable for use herein are given below.

Water

Since the present compositions are beverage compositions, water is typically utilized in the methods and kits of the present invention. As used herein, the term "water" includes the total amount of water present in the composition. Accordingly, "water" includes water from flavor agents, sugar
 15 syrups, and other sources, *e.g.*, gum solutions. Water of hydration of any solids present in the compositions is also included. Wherein water is included, water is included at levels from about 0.1% to about 99.999%, preferably from about 5% to about 99%, still preferably from about 50% to about 99%, more preferably from about 70% to about 95%, and most preferably from about 85% to about 93%, by weight of the product.

One of ordinary skill will recognize that the compounds utilized herein may also have activity as a preservative when utilized in beverage compositions, it is often preferred to utilize compositions which are also optimized for preservative activity. Therefore, as one will further understand based on recent disclosures, the water hardness may be adjust for optimum preservative activity of the compound used herein. The term "hardness" with respect to the water herein generally
 25 refers to the presence of certain cations in water. For purposes of the present invention, hardness of the added water component is calculated according to the Association of Official Analytical Chemists (AOAC) standards set forth in Official Methods of Analysis, published by the AOAC, Arlington, Virginia, pp. 627 - 628 (14th Ed., 1984). Under AOAC standards, hardness is the sum of CaCO₃ equivalents (mg / L) in water, which sum is obtained by multiplying the concentrations (mg /
 30 L) found of the following cations in the water by the factors (see Table 1, below).

Table 1

Cation	Factor
Ca	2.497
Mg	4.116
Sr	1.142
Fe	1.792
Al	5.564
Zn	1.531
Mn	1.822

Compounds which impart hardness to water are primarily magnesium and calcium carbonates, bicarbonates, sulfates, chlorides, and nitrates, although other compounds which can contribute polyvalent cations to water can also impart hardness. Water based on hardness is normally classified as soft (0 - 60 ppm water hardness), moderately hard (61 - 120 ppm water hardness), and very hard (over 180 ppm). It is preferred herein that the compositions have a water hardness of about 0 ppm to about 120 ppm, more preferably from about 0 ppm to about 60 ppm, and most preferably from about 0 ppm to about 30 ppm. As it is especially preferred, for example, that the compositions herein are substantially free of calcium, such preference for relatively low water hardness (moderately hard or soft) is consistent with the present invention.

Excessively hard water may be treated or softened by known and conventional methods to reduce hardness to appropriate levels. Accordingly, wherein water is treated, this treated water can then be used as the added water component of the beverage product.

Beverage Emulsions

Beverage compositions utilized herein may optionally, but preferably, comprise from about 0.2% to about 5%, preferably from about 0.5% to about 3%, and most preferably from about 0.8% to about 2%, of a beverage emulsion. This beverage emulsion can be either a cloud emulsion or a flavor emulsion.

For cloud emulsions, the clouding agent can comprise one or more fats or oils stabilized as an oil-in-water emulsion using a suitable food grade emulsifier. Any of a variety of fats or oils may be employed as the clouding agent, provided that the fat or oil is suitable for use in foods and / or beverages. Preferred are those fats and oils that have been refined, bleached and deodorized to remove off-flavors. Especially suitable for use as clouding agents are those fats that are organoleptically neutral. These include fats from the following sources: vegetable fats such as soybean, corn, safflower, sunflower, cottonseed, canola, and rapeseed; nut fats such as coconut, palm,

and palm kernel; and synthetic fats. See e.g., Kupper et al., U.S. Patent No. 4,705,691, issued November 10, 1987, for suitable fat or oil clouding agents.

Any suitable food grade emulsifier can be used that can stabilize the fat or oil clouding agent as an oil-in-water emulsion. Suitable emulsifiers include gum acacia, modified food starches (e.g., alkenylsuccinate modified food starches), anionic polymers derived from cellulose (e.g., carboxymethylcellulose), gum ghatti, modified gum ghatti, xanthan gum, tragacanth gum, guar gum, locust bean gum, pectin, and mixtures thereof. See e.g., Kupper et al., U.S. Patent No. 4,705,691, issued November 10, 1987. Modified starches treated to contain hydrophobic as well as hydrophilic groups, such as those described in Caldwell et al., U.S. Patent 2,661,349, are preferred emulsifiers for use as herein. Octenyl succinate (OCS) modified starches such as those described in Marotta et al., U.S. Patent 3,455,838 and Barndt et al., U.S. Patent 4,460,617 are especially preferred emulsifiers.

The clouding agent can be combined with a weighting agent to provide a beverage opacifier that imparts a total or partial opaque effect to the beverage without separating out and rising to the top. The beverage opacifier provides the appearance to the consumer of a juice-containing beverage. Any suitable weighting oil can be employed in the beverage opacifier. Typical weighting oils include brominated vegetable oil, glycerol ester of wood rosin (ester gum), sucrose acetate isobutyrate (SAIB) and other sucrose esters, gum damar, colophony, gum elemi, or others known to those skilled in the art. Other suitable weighting agents include brominated liquid polyol polyesters which are nondigestible. See e.g., Brand et al., U.S. Patent 4,705,690, issued November 10, 1987.

The cloud/opacifier emulsion is prepared by mixing the clouding agent with the weighting agent (for opacifier emulsions), the emulsifier and water. The emulsion typically contains from about 0.1% to about 25% clouding agent, from about 1% to about 20% weighting oil agent (in the case of opacifier emulsions), from about 1% to about 30% emulsifiers, and from about 25% to about 97.9% water (or *quantum satis*).

The particle size of the water-insoluble components of the emulsion is reduced by employing a suitable apparatus known in the art. Because the ability of emulsifying agents to hold oil in suspension is proportional to particle size, emulsions of particles with diameters of about 0.1 to about 3.0 microns are suitable. Preferably, the particles are about 2.0 microns or less in diameter. Most preferred is an emulsion in which substantially all the particles are 1.0 microns or less in diameter. The particle size is reduced by passing the mixture through an homogenizer, colloid mill or turbine-type agitator. Usually one or two passes is sufficient. See e.g., Kupper et al., U.S. Patent 4,705,691, issued November 10, 1987.

Flavor emulsions useful in beverage products of the present invention comprise one or more suitable flavor oils, extracts, oleoresins, essential oils and the like, known in the art for use as flavorants in beverages. This component can also comprise flavor concentrates such as those derived from concentration of natural products such as fruits. Terpeneless citrus oils and essences can also

be used herein. Examples of suitable flavors include, for example, fruit flavors such as orange, lemon, lime and the like, cola flavors, tea flavors, coffee flavors, chocolate flavors, dairy flavors. These flavors can be derived from natural sources such as essential oils and extracts, or can be synthetically prepared. The flavor emulsion typically comprises a blend of various flavors and can be employed in the form of an emulsion, alcoholic extract, or spray dried. The flavor emulsion can also include clouding agents, with or without weighting agents, as previously described. See e.g., Kupper et al., U.S. Patent 4,705,691, issued November 10, 1987.

Flavor emulsions are typically prepared in the same manner as cloud/opacifier emulsions by mixing one or more flavoring oils (from about 0.001% to about 20%) with an emulsifying agent (from about 1% to about 30%) and water. (The oil clouding agents can also be present). Emulsions of particles with diameters of from about 0.1 to about 3.0 microns are suitable. Preferably, the particles are about 2.0 microns or less in diameter. Most preferably, the particles are about 1.0 microns or less in diameter. The emulsifying agent coats the particularized flavor oil to aid in preventing coalescence and in maintaining an appropriate dispersion. The viscosity and specific gravity of the flavor emulsion are regulated to be compatible with the finished beverage. See e.g., Kupper et al., U.S. Patent 4,705,691, issued November 10, 1987.

Flavor Agents

The beverage compositions utilized herein may comprise one or more flavor agents selected from fruit juice, tea solids, milk solids, fruit flavors, botanical flavors, and mixtures thereof. When fruit juice is included, the beverages of the present invention can comprise from about 0.1% to about 40%, preferably from about 1% to about 20%, more preferably from about 2% to about 10%, and most preferably from about 3% to about 6%, fruit juice. (As measured herein, the weight percentage of fruit juice is based on a single strength 2° to 16° Brix fruit juice). The fruit juice can be incorporated into the beverage as a puree, comminute, or as a single strength or concentrated juice. Especially preferred is incorporation of the fruit juice as a concentrate with a solids content (primarily as sugar solids) of from about 20° to about 80° Brix.

The fruit juice can be any citrus juice, non-citrus juice, or mixture thereof, which are known for use in dilute juice beverages. The juice can be derived from, for example, apple, cranberry, pear, peach, plum, apricot, nectarine, grape, cherry, currant, raspberry, gooseberry, elderberry, blackberry, blueberry, strawberry, lemon, lime, mandarin, orange, grapefruit, cupuacu, potato, tomato, lettuce, celery, spinach, cabbage, watercress, dandelion, rhubarb, carrot, beet, cucumber, pineapple, coconut, pomegranate, kiwi, mango, papaya, banana, watermelon, passion fruit, tangerine, and cantaloupe. Preferred juices are derived from apple, pear, lemon, lime, mandarin, grapefruit, cranberry, orange, strawberry, tangerine, grape, kiwi, pineapple, passion fruit, mango, guava, raspberry and cherry. Citrus juices, preferably grapefruit, orange, lemon, lime, and mandarin juices, as well as juices

derived from mango, apple, passion fruit, and guava, as well as mixtures of these juices are most preferred.

Fruit flavors may also be utilized. As described above with respect to flavor emulsions, fruit flavors may be derived from natural sources such as essential oil and extracts, or can be synthetically prepared. Fruit flavors may be derived from fruits through processing, particularly concentrating. Wherein fruit juices are concentrated or evaporated, the water which is removed or the condensate contains volatile substances which comprise the flavor of the fruit. Often, such flavor is added to a juice concentrate to enhance the flavor thereof. The condensate may also be used to flavor "near waters" (lightly flavored water).

Botanical flavors may also be utilized. As used herein, the term "botanical flavor" refers to a flavor derived from parts of a plant other than the fruit; *i.e.*, derived from nuts, bark, roots, and / or leaves. Also included within the term "botanical flavor" are synthetically prepared flavors made to simulate botanical flavors derived from natural sources. Botanical flavors can be derived from natural sources such as essential oils and extracts, or can be synthetically prepared. Suitable botanical flavors include jamaica, kola, marigold, chrysanthemum, chamomile, ginger, valerian, yohimbe, hops, eriodictyon, ginseng, bilberry, rice, red wine, mango, peony, lemon balm, nut gall, oak chip, lavender, walnut, gentian, luohanguo, cinnamon, angelica, aloe, agrimony, yarrow and mixtures thereof.

Tannic acid or other similar acids can be used to provide an astringent taste to the beverage. From about 0.001% to about 10% tannic acid is used. Other flavor enhancers, as well as flavorants such as chocolate and vanilla can also be used.

Wherein tea solids are included, the beverages of the present invention can comprise from about 0.01% to about 1.2%, preferably from about 0.05% to about 0.8%, by weight of the beverage product, of tea solids. The term "tea solids" as used herein means solids extracted from tea materials including those materials obtained from the genus *Camellia* including *C. sinensis* and *C. assamica*, for instance, freshly gathered tea leaves, fresh green tea leaves that are dried immediately after gathering, fresh green tea leaves that have been heat treated before drying to inactivate any enzymes present, unfermented tea, instant green tea, and partially fermented tea leaves. Green tea materials are tea leaves, tea plant stems, and other plant materials that are related and which have not undergone substantial fermentation to create black teas. Members of the genus *Phyllanthus*, *Catechu gambir* and *Uncaria* family of tea plants can also be used. Mixtures of unfermented and partially fermented teas can be used.

Tea solids for use in beverages of the present invention can be obtained by known and conventional tea solid extraction methods. A particularly preferred source of green tea solids can be obtained by the method described in Ekanayake et al., U.S. Application Serial No. 08/606,907, filed February 26, 1996. Tea solids so obtained will typically comprise caffeine, theobromine, proteins,

amino acids, minerals and carbohydrates. Suitable beverages containing tea solids can be formulated according to Tsai et al., U.S. Patent 4,946,701, issued August 7, 1990. See also, Ekanayake et al., U.S. Patent 5,427,806, issued June 26, 1995, for a suitable sources of green tea solids for use in the present invention.

Beverage compositions utilized herein may also comprise milk solids. These milk solids can be derived from various sources including whole milk, skim milk, condensed milk, and dried milk powder. As used herein, the term "milk" will be used to describe an aqueous dispersion of milk solids, such as fluid (whole or skim milk) or non-fat dry milk or condensed milk diluted with water. The amount of milk included typically ranges from about 5% to about 99.8%, preferably from about 5% to about 75%, more preferably from about 5% to about 40%, and most preferably from about 5% to about 15%. The amount of non-fat milk solids correlating to these levels of milk solids is in the range of from about 0.5% to about 8.2%, from about 0.5% to about 6.2%, from about 0.5% to about 3.3%, and from about 0.5% to 1.2% of the beverage, respectively.

Thickeners

Beverages compositions utilized herein, especially dilute juice beverages and beverages comprising tea solids may further comprise thickeners, including xanthan gum, carboxymethylcellulose, propylene glycol alginate, gellan gum, guar gum, pectin, tragacanth gum, gum acacia, locust bean gum, gum arabic, gelatin, as well as mixtures of these thickeners. These thickeners are typically included in the beverages of the present invention at levels up to about 0.1%, depending on the particular thickener involved and the viscosity effects desired.

Sweeteners

The beverage compositions utilized herein can, and typically will, contain an effective amount of one or more sweeteners, including carbohydrate sweeteners and natural and/or artificial no/low calorie sweeteners. As stated herein above, it has been surprisingly discovered that inclusion of one or more sweeteners may not be deleterious to the treatment of dental erosion when utilized in the presently described beverage compositions. The amount of the sweetener used in the beverages of the present invention typically depends upon the particular sweetener used and the sweetness intensity desired. For no/low calorie sweeteners, this amount varies depending upon the sweetness intensity of the particular sweetener.

The beverages of the present invention can be sweetened with any of the carbohydrate sweeteners, preferably monosaccharides and / or disaccharides. Sweetened beverages will typically comprise from about 0.1% to about 20%, most preferably from about 6 to about 14%, sweetener. These sugars can be incorporated into the beverages in solid or liquid form but are typically, and preferably, incorporated as a syrup, most preferably as a concentrated syrup such as high fructose corn syrup. For purposes of preparing beverages of the present invention, these sugar sweeteners can

be provided to some extent by other components of the beverage such as, for example, the fruit juice component and / or flavors.

Preferred sugar sweeteners for use in beverage products of the present invention are sucrose, fructose, glucose, and mixtures thereof. Fructose can be obtained or provided as liquid fructose, high fructose corn syrup, dry fructose or fructose syrup, but is preferably provided as high fructose corn syrup. High fructose corn syrup (HFCS) is commercially available as HFCS-42, HFCS-55 and HFCS-90, which comprise 42%, 55% and 90%, respectively, by weight of the sugar solids therein, as fructose. Other naturally occurring sweeteners or their purified extracts, such as glycyrrhizin, the protein sweetener thaumatin, the juice of Luo Han Guo disclosed in, for example, Fischer et al., U. S. Patent No. 5,433,965, issued July 18, 1995, and the like can also be used in the beverages of the present invention.

Suitable no/low calorie sweeteners include saccharin, cyclamates, acesulfame K (Sunette®), L-aspartyl-L-phenylalanine lower alkyl ester sweeteners (e.g., aspartame); L-aspartyl-D-alanine amides disclosed in Brennan et al., U.S. Patent No. 4,411,925; L-aspartyl-D-serine amides disclosed in Brennan et al., U.S. Patent 4,399,163; L-aspartyl-L-1-hydroxymethylalkaneamide sweeteners disclosed in Brand, U.S. Patent No. 4,338,346; L-aspartyl-1-hydroxyethylalkaneamide sweeteners disclosed in Rizzi, U.S. Patent No. 4,423,029; L-aspartyl-D-phenylglycine ester and amide sweeteners disclosed in Janusz, European Patent Application 168,112, published January 15, 1986; N-[N-(3,3-dimethylbutyl)-L- α -aspartyl]-L-phenylalanine 1-methyl ester sweeteners disclosed in Gerlat et al., WO 99/30576, assigned to The Nutrasweet Co., published June 24, 1999; and the like and mixtures thereof. A particularly preferred low calorie sweetener is aspartame.

Coloring Agent

Small amounts of coloring agents may be utilized in the beverage compositions herein. FD&C dyes (e.g., yellow #5, blue #2, red # 40) and / or FD&C lakes are preferably used. By adding the lakes to the other powdered ingredients, all the particles, in particular the colored iron compound, are completely and uniformly colored and a uniformly colored beverage mix is attained. Preferred lake dyes which may be used in the present invention are the FDA-approved Lake, such as Lake red #40, yellow #6, blue #1, and the like. Additionally, a mixture of FD&C dyes or a FD&C lake dye in combination with other conventional food and food colorants may be used. Riboflavin and β -carotene may also be used. The exact amount of coloring agent used will vary, depending on the agents used and the intensity desired in the finished product. The amount can be readily determined by one skilled in the art. Generally, if utilized, the coloring agent should be present at a level of from about 0.0001% to about 0.5%, preferably from about 0.001% to about 0.1%, and most preferably from about 0.004% to about 0.1%, by weight of the product.

Nutrients

The compositions herein are optionally, but preferably, fortified with one or more nutrients, especially one or more vitamins and / or minerals. The U.S. Recommended Daily Intake (USRDI) for vitamins and minerals are defined and set forth in the Recommended Daily Dietary Allowance-Food and Nutrition Board, National Academy of Sciences-National Research Council.

Unless otherwise specified herein, wherein a given mineral is present in the composition, the composition typically comprises at least about 1%, preferably at least about 5%, more preferably from about 10% to about 200%, even more preferably from about 40% to about 150%, and most preferably from about 60% to about 125% of the USRDI of such mineral. Unless otherwise specified herein, wherein a given mineral is present in the composition, the composition comprises at least about 1%, preferably at least about 5%, more preferably from about 10% to about 200%, even more preferably from about 20% to about 150%, and most preferably from about 25% to about 120% of the USRDI of such mineral.

Non-limiting examples of such vitamins and minerals, include niacin, thiamin, folic acid, pantothenic acid, biotin, vitamin A, vitamin C, vitamin B₂, vitamin B₃, vitamin B₆, vitamin B₁₂, vitamin D, vitamin E, vitamin K, iron, zinc, copper, iodine, chromium, and molybdenum. Preferably, wherein a vitamin or mineral is utilized the vitamin or mineral is selected from niacin, thiamin, folic acid, iodine, vitamin A, vitamin C, vitamin B₆, vitamin B₁₂, vitamin D, vitamin E, iron, and zinc. Preferably, at least one vitamin is selected from vitamin C, vitamin B₆, vitamin B₁₂, vitamin E, pantothenic acid, niacin, and biotin.

Commercially available vitamin A sources may also be included in the present compositions. Vitamin A can be provided, for example, as vitamin A palmitate (retinol palmitate) and / or as beta-carotene. The vitamin A may be in the form of, for example, an oil, beadlets or encapsulated. As used herein, "vitamin A" includes, but is not limited to, vitamin A, β -carotene, retinol palmitate, and retinol acetate. Wherein vitamin A is present in the compositions herein, the product comprises at least about 1%, preferably at least about 5%, more preferably from about 10% to about 200%, even more preferably from about 15% to about 150%, and most preferably from about 20% to about 120% of the USRDI of such vitamin. Wherein vitamin A is present in the compositions herein, it is especially preferred to include about 25% of the USRDI of vitamin A. The quantity of vitamin A to be added is dependent on processing conditions and the amount of vitamin A deliver desired after storage. Preferably, wherein vitamin A is included within the present compositions, the compositions comprise from about 0.0001% to about 0.2%, more preferably from about 0.0002% to about 0.12%, also preferably from about 0.0003% to about 0.1%, even more preferably from about 0.0005% to about 0.08%, and most preferably from about 0.001% to about 0.06% of vitamin A, by weight of the product.

Commercially available sources of vitamin B₂ (also known as riboflavin) may be utilized in the present compositions. Wherein vitamin B₂ is present in the compositions herein, the product comprises at least about 1%, preferably at least about 5%, more preferably from about 5% to about 200%, even more preferably from about 10% to about 150%, and most preferably from about 10% to about 120% of the USRDI of such vitamin. Wherein vitamin B₂ is present in the compositions herein, it is especially preferred to include from about 15% to about 35% of the USRDI of vitamin B₂.

Commercially available sources of vitamin C can be used herein. Encapsulated ascorbic acid and edible salts of ascorbic acid can also be used. Wherein vitamin C is present in the compositions herein, the product comprises at least about 1%, preferably at least about 5%, more preferably from about 10% to about 200%, even more preferably from about 20% to about 150%, and most preferably from about 25% to about 120% of the USRDI of such vitamin. Wherein vitamin C is present in the compositions herein, it is especially preferred to include about 100% of the USRDI of vitamin C. The quantity of vitamin C to be added is dependent on processing conditions and the amount of vitamin C deliver desired after storage. Preferably, wherein vitamin C is included within the present compositions, the compositions comprise from about 0.005% to about 0.2%, more preferably from about 0.01% to about 0.12%, also preferably from about 0.02% to about 0.1%, even more preferably from about 0.02% to about 0.08%, and most preferably from about 0.03% to about 0.06% of vitamin C, by weight of the product.

Commercial sources of iodine, preferably as an encapsulated iodine may be utilized herein. Other sources of iodine include iodine-containing salts, e.g., sodium iodide, potassium iodide, potassium iodate, sodium iodate, or mixtures thereof. These salts may be encapsulated.

Nutritionally supplemental amounts of other vitamins which may be incorporated herein include, but are not limited to, vitamins B₆ and B₁₂, folic acid, niacin, pantothenic acid, folic acid, vitamin D, and vitamin E. Wherein the product comprises one of these vitamins, the product preferably comprises at least 5%, preferably at least 25%, and most preferably at least 35% of the USRDI for such vitamin.

Minerals which may optionally be included in the compositions herein are, for example, magnesium, zinc, iodine, iron, and copper. Any soluble salt of these minerals suitable for inclusion edible compositions can be used, for example, magnesium citrate, magnesium gluconate, magnesium sulfate, zinc chloride, zinc sulfate, potassium iodide, copper sulfate, copper gluconate, and copper citrate.

Iron may also be utilized in the compositions and methods of the present invention. Acceptable forms of iron are well-known in the art. The amount of iron compound incorporated into the product will vary widely depending upon the level of supplementation desired in the final product

and the targeted consumer. Iron fortified compositions of the present invention typically contain from about 5% to about 100%, preferably from about 15% to about 50%, and most preferably about 20% to about 40% of the USRDI for iron.

Ferrous iron is typically better utilized by the body than ferric iron. Highly bioavailable ferrous salts that can be used in the ingestible compositions of the present invention are ferrous sulfate, ferrous fumarate, ferrous succinate, ferrous gluconate, ferrous lactate, ferrous tartarate, ferrous citrate, ferrous amino acid chelates, as well as mixtures of these ferrous salts. While ferrous iron is typically more bioavailable, certain ferric salts can also provide highly bioavailable sources of iron. Highly bioavailable ferric salts that can be used in the food or beverage compositions of the present invention are ferric saccharate, ferric ammonium citrate, ferric citrate, ferric sulfate, as well as mixtures of these ferric salts. Combinations or mixtures of highly bioavailable ferrous and ferric salts can be used in these edible mixes and ready-to-serve beverages. The preferred sources of highly bioavailable iron are ferrous fumarate and ferrous amino acid chelates.

Ferrous amino acid chelates particularly suitable as highly bioavailable iron sources for use in the present invention are those having a ligand to metal ratio of at least 2:1. For example, suitable ferrous amino acid chelates having a ligand to metal mole ratio of two are those of formula:



where L is an alpha amino acid, dipeptide, tripeptide, or quadrupetide ligand. Thus, L can be any ligand which is a naturally occurring alpha amino acid selected from alanine, arginine, asparagine, aspartic acid, cysteine, cystine, glutamine, glutamic acid, glycine, histidine, hydroxyproline, isoleucine, leucine, lysine, methionine, ornithine, phenylalanine, proline, serine, threonine, tryptophan, tyrosine, and valine; or dipeptides, tripeptides, or quadrupetides formed by any combination of these alpha amino acids. See e.g., Ashmead et al., U.S. Patent No. 4,863,898, issued September 5, 1989; Ashmead, U.S. Patent No. 4,830,716, issued May 16, 1989; and Ashmead, U.S. Patent No. 4,599,152, issued July 8, 1986, all of which are incorporated by reference. Particularly preferred ferrous amino acid chelates are those where the reacting ligands are glycine, lysine, and leucine. Most preferred is the ferrous amino acid chelate sold under the mark Ferrochel® (Albion Laboratories, Salt Lake City, Utah) wherein the ligand is glycine.

In addition to these highly bioavailable ferrous and ferric salts, other sources of bioavailable iron can be included in the food and beverage compositions of the present invention. Other sources of iron particularly suitable for fortifying compositions of the present invention included certain iron-sugar-carboxylate complexes. In these iron-sugar-carboxylate complexes, the carboxylate provides the counterion for the ferrous (preferred) or ferric iron. The overall synthesis of these iron-sugar-carboxylate complexes involves the formation of a calcium-sugar moiety in aqueous media (for example, by reacting calcium hydroxide with a sugar, reacting the iron source (such as ferrous

ammonium sulfate) with the calcium-sugar moiety in aqueous media to provide an iron-sugar moiety, and neutralizing the reaction system with a carboxylic acid (the "carboxylate counterion") to provide the desired iron-sugar- carboxylate complex. Sugars that can be used to prepare the calcium-sugar moiety include any of the ingestible saccharidic materials, and mixtures thereof, such as glucose, sucrose and fructose, mannose, galactose, lactose, maltose, and the like, with sucrose and fructose being the more preferred. The carboxylic acid providing the "carboxylate counterion" can be any ingestible carboxylic acid such as citric acid, malic acid tartaric acid, lactic acid, succinic acid, propionic acid, etc., as well as mixtures of these acids.

These iron-sugar-carboxylate complexes can be prepared in the manner described in, *e.g.*, Nakel et al., U.S. Patent Nos. 4,786,510 and 4,786,518, issued November 22, 1988, both of which are incorporated by reference. These materials are referred to as "complexes", but they may exist in solution as complicated, highly hydrated, protected colloids; the term "complex" is used for the purpose of simplicity.

Zinc may also be utilized in the compositions and methods of the present invention. Acceptable forms of zinc are well-known in the art. Zinc fortified compositions of the present invention typically contain from about 5% to about 100%, preferably from about 15% to about 50%, and most preferably about 25% to about 45% of the USRDI for zinc. The zinc compounds which can be used in the present invention can be in any of the commonly used forms such as, *e.g.*, zinc sulfate, zinc chloride, zinc acetate, zinc gluconate, zinc ascorbate, zinc citrate, zinc aspartate, zinc picolinate, amino acid chelated zinc, and zinc oxide. Zinc gluconate and amino acid chelated zinc are particularly preferred.

Carbonation Component

Carbon dioxide can be introduced into the water which is mixed with a beverage syrup or into the beverage composition after dilution to achieve carbonation. The carbonated beverage can be placed into a container, such as a bottle or can, and then sealed. Any conventional carbonation methodology may be utilized to make carbonated beverage products of this invention. The amount of carbon dioxide introduced into the beverage will depend upon the particular flavor system utilized and the amount of carbonation desired.

Soluble Fibers

One or more soluble fibers may also optionally be included in the compositions utilized herein. Soluble fibers which can be used singularly or in combination in all embodiments of the present invention include but are not limited to pectins, psyllium, guar gum, xanthan, alginates, gum arabic, fructo-oligosaccharides, inulin, agar, and carrageenan. These soluble fibers may also serve as stabilizing agents in the various embodiments of this invention.

Pectin and fructo-oligosaccharides are the preferred soluble fibers herein. Even more preferably, pectin and fructo-oligosaccharides are used in combination. The preferred ratio of pectin

to fructo-oligosaccharide is from about 3:1 to about 1:3, by weight of the composition. The preferred pectins have a degree of esterification higher than about 65%.

The preferred fructo-oligosaccharides are a mixture of fructo-oligosaccharides composed of a chain of fructose molecules linked to a molecule of sucrose. Most preferably, they have a nystose to kestose to fructosyl-nystose ratio of about 40:50:10, by weight of the composition. Preferred fructo-oligosaccharides may be obtained by enzymatic action of fructosyltransferase on sucrose such as those which are, for example, commercially available from Beghin-Meiji Industries, Neuilly-sur-Seine, France.

Preferred pectins are obtained by hot acidic extraction from citrus peels and may be obtained, for example, from Danisco Co., Braband, Denmark.

Wherein a soluble fiber is utilized, the desired total level of soluble dietary fiber for the present compositions of the present invention is typically from about 0.01% to about 15%, preferably from about 0.1% to about 5%, and most preferably from about 0.1% to about 2%. The total amount of soluble dietary fiber includes any added soluble dietary fiber as well as any soluble dietary fiber naturally present in any other component of the present invention.

Preservatives

Optionally, one or more preservatives may additionally be utilized herein. Preferred preservatives include, for example, sorbate and benzoate. The polyphosphate compounds described herein above are also quite useful as preservatives.

Preferably, wherein a preservative other than the present polyphosphate compound is utilized herein, one or more sorbate or benzoate preservative (or mixtures thereof) is utilized. Sorbate and benzoate preservatives suitable for use in the present invention include sorbic acid, benzoic acid, and salts thereof, including (but not limited to) calcium sorbate, sodium sorbate, potassium sorbate, calcium benzoate, sodium benzoate, potassium benzoate, and mixtures thereof. Sorbate preservatives are particularly preferred. Potassium sorbate is particularly preferred for use in the present invention.

Wherein a product comprises a sorbate and / or benzoate, the compositions of the present invention preferably comprise from about 0.0005% to about 0.04% of the sorbate and / or benzoate, more preferably from about 0.001% to about 0.035% of the sorbate and / or benzoate, and most preferably from about 0.003% to about 0.03% of the sorbate and / or benzoate, by weight of the composition. Wherein the composition comprises a mixture of one or more sorbates and / or benzoates, the total concentration of such preservatives is preferably maintained within these ranges.

Analytical Methods

Beverage compositions, for example, soft drink beverages (e.g., cola beverages) and fruit juice beverages, may cause the consumer of the beverage to experience dental erosion. Such dental erosion is caused wherein the beverage composition is acidic in nature, i.e., exhibits a pH of about 5

or below. As such, it is important to measure the erosive properties (or lack thereof) of typical beverages and the beverage compositions defined herein. Dental erosion may be measured using standard methods, however, the method described in Rugg-Gunn et al., "Comparison of Erosion of Dental Enamel by Four Drinks Using an Intra-Oral Appliance", *Caries Research*, Vol. 32, pp. 337 - 343 (1998). This method is summarized generally as follows.

Upper removable oral appliances having a washer one slab on either side of the midline of the palate are constructed for one or more human test subjects. The slab is constructed such that the two slabs may be simultaneously immersed in test beverage during the experimental period. The slabs are composed of human enamel (sterilized by autoclaving), such as that obtained from extraction of human molar teeth. The slabs are profiled using a surface profiler (Surfometer SF220, Planer Products Ltd.). Each slab is profiled before and after an experimental period of six days. Each profile tracing is digitised and distance from mean surface of enamel to the line joining the surface of the washer is calculated. This distance is average over the three profiles for each enamel slab. The mean distance at baseline is subtracted from the mean distance at the end of an experimental period of six days to give a mean depth of enamel loss during that experimental period.

During an experimental period of six days, each test subject wears an appliance with slabs. Appliances are removed during meals and are lightly brushed or rinsed once a day with a standard dentifrice. Four times per day, the 2 sides of each slab are inserted for a 15 minute period into a predetermined beverage composition. Each side is inserted into a different beverage composition; the beverage composition into which any one slab is inserted remains constant for the six day experimental period. The means change depth of enamel, for each test subject, is calculated. The erosive potential of each beverage, for this analytical method, is determined based on such calculations.

Using the above generalized procedure, the following observations are made:

- (a) A fruit juice composition not containing a polyphosphate compound as defined herein, and having a pH of less than about 5, is more erosive to the enamel than distilled water;
- (b) A fruit juice composition not containing a polyphosphate compound as defined herein, and having a pH of less than about 5, is about as erosive as a standard cola (carbonated) beverage;
- (c) A fruit juice composition not containing a polyphosphate compound as defined herein, and having a pH of less than about 5, is more erosive than a similar fruit juice composition supplemented with calcium;
- (d) A fruit juice composition not containing a polyphosphate compound as defined herein but supplemented with calcium, and having a pH of less than about 5, is more erosive than distilled water;

- (e) A fruit juice composition not containing a polyphosphate compound as defined herein, and having a pH of less than about 5, is more erosive than a similar fruit juice composition supplemented with a polyphosphate compound as defined herein; and
- (f) A fruit juice composition supplemented with a polyphosphate compound as defined herein, and having a pH of less than about 5, is no more erosive than distilled water.

Methods of Making the Beverage Compositions Utilized Herein

The beverage compositions utilized herein are prepared according to methods which are standard in the art. For example, the beverage compositions used herein can be prepared by conventional methods for formulating dilute juice beverages. Such conventional methods may involve hot packing or aseptic packaging operations.

Methods for making dilute juice beverages, for example, are described in Nakel et al., U.S. Patent No. 4,737,375. Methods for making beverage compositions are also described by Woodroof and Phillips, Beverages: Carbonated & Noncarbonated, AVI Publishing Co., revised ed. 1981; and by Thorner and Herzberg, Non-Alcoholic Food Service Beverage Handbook, AVI Publishing Co., 2nd Ed., 1978).

One method for preparing the beverage compositions herein involves making a beverage concentrate, adding the concentrate to a sugar syrup containing the polyphosphate compound defined herein, and then trimming the mixture with water, sugar syrup, and beverage concentrate to obtain the requisite acidity and material composition. All added water used in such preparation is adjusted to the desired hardness. In such a method, the beverage concentrate may be prepared by admixing to water, for example, an acidulant or acidic buffer, vitamins, flavorants, and preservative. An oil-in-water emulsion, which provides opacity and texture to the beverage compositions, can be added to the concentrate. The sugar syrup for use in preparing the beverage compositions is separately prepared by adding sugar syrup (e.g., high fructose corn syrup) to water, then adding (for example) ascorbic acid, the polyphosphate compound, and thickening agents to the syrup. Additional preservative may be added to the resulting sugar syrup. The sugar syrup and concentrate are combined to form a beverage composition. The beverage composition can be trimmed with added water, sugar syrup, and beverage concentrate to achieve the requisite acidity and composition of the beverage composition of utilized in the present invention. It should be understood that the foregoing serves as a non-limiting example and that other methods may be utilized to prepare the beverage compositions herein. Other well known and conventional variations of the foregoing can, therefore, be utilized to prepare the beverage compositions herein.

EXAMPLES

The following provides specific embodiments of beverage compositions (and processes for preparing them) which may be advantageously used in the methods and kits of the present invention.

These specific embodiments are illustrative of the compositions used herein and are not intended to be limited.

Components for each composition are typically admixed in the order in which they appear herein. Sodium hexametaphosphate for each composition is typically admixed under high sheer mixing to insure solubility.

Example 1

Component	Amount
High Fructose Corn Syrup (HFCS) - 55*	13%
Fruit Juice Concentrate	0.7%
Potassium Sorbate	0.065%
Sodium Hexametaphosphate	0.1%
Citric Acid	Titrate to pH of 3.3
Water (Hardness < 30 ppm)	<i>quantum satis</i>

*High Fructose Corn Syrup containing 55% fructose

The beverage composition containing the above components is ingested by a 7-year-old male human daily for a 12 week period. Prior to this period, the 7-year-old male human has average dental health relative to humans of similar age. During this period, the 7-year-old male human experiences reduced dental erosion, as measured by erosion of enamel, relative to humans of similar age which ingest typical low pH beverages not comprising a polyphosphate compound as described herein.

Example 2

Component	Amount
High Fructose Corn Syrup (HFCS) - 55	13%
Tea Solids	0.1%
Potassium Sorbate	0.065%
Sodium Hexametaphosphate	0.1%
Citric Acid	Titrate to pH of 3.3
Water (Hardness < 30 ppm)	<i>quantum satis</i>

The beverage composition containing the above components is ingested by a 24-year-old human daily for a 2 week period. Prior to this period, the 24-year-old human has average dental health relative to humans of similar age. During this period, the 24-year-old human experiences reduced dental erosion, as measured by erosion of enamel, relative to humans of similar age which ingest low pH cola beverages not comprising a polyphosphate compound as described herein.

Example 3*

Component	Amount
High Fructose Corn Syrup (HFCS) - 55	14.7%
Fruit Juice Concentrate	1.15%
Natural Gums	0.01%
Potassium Sorbate	0.035%
Sodium Hexametaphosphate (n = 21)	0.1%
Organic Acids	0.48%
Vitamins	0.005%
Coloring Agents	0.003%
Water	<i>quantum satis</i>

*The pH of the composition is from about 2.9 to about 3.3.

Example 4

Component	Amount
Sugar	9.5%
Fruit Juices	5.5%
Natural Gums	0.15%
Carboxymethyl cellulose	0.05%
Potassium Sorbate	0.035%
Sodium Hexametaphosphate (n = 21)	0.1%
Organic Acids	0.7%
Beta-carotene, Vitamin B ₁ , Vitamin B ₆ , and Vitamin C	based on desired nutrient level
Coloring Agents	0.003%
Water	<i>quantum satis</i>

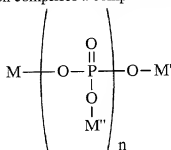
A beverage composition of either the above Example 3 or Example 4, is ingested by a 5-year-old human child daily for a 3 week period. Prior to this period, the 5-year-old human has average dental health relative to humans of similar age. During this period, the 5-year-old human experiences reduced dental erosion, as measured by erosion of enamel, relative to humans of similar age which ingest low pH fruit juice beverages not comprising a polyphosphate compound as described herein.



WHAT IS CLAIMED IS:

1. A method of treating dental erosion comprising orally administering to a mammal a beverage composition having a pH of less than about 5;

wherein the beverage composition comprises a compound having the structure:



wherein n is an integer averaging from about 7 to about 100 and M, M', and M'' are each, independently, selected from the group consisting of sodium and potassium.

2. A method according to Claim 1 wherein the beverage composition has a pH from about 2 to about 4.5.
3. A method according to Claim 2 wherein the beverage composition further comprises a sweetener.
4. A method according to Claim 3 wherein M, M', and M'' are each sodium.
5. A method according to Claim 4 wherein n is an integer averaging from about 10 to about 30.
6. A method according to Claim 5 wherein the beverage composition is substantially free of one or more components selected from the group consisting of calcium and fluoride.
7. A method according to Claim 6 wherein n is an integer averaging from about 13 to about 25.
8. A method according to Claim 7 wherein the beverage composition has a pH from about 2.7 to about 3.5.
9. A method according to Claim 8 wherein the beverage composition comprises from about 0.1% to about 20% of the sweetener, by weight of the composition.
10. A method according to Claim 9 wherein n is an integer averaging from about 19 to about 25.

11. A kit comprising:

- (a) a beverage composition according to Claim 1; and
- (b) information that use of the beverage composition provides treatment against dental erosion.

12. A kit according to Claim 11 wherein the beverage composition has a pH from about 2 to about 4.5.

13. A kit according to Claim 12 wherein the beverage composition further comprises a sweetener.

14. A kit according to Claim 13 wherein M, M', and M'' are each sodium.

15. A kit according to Claim 14 wherein n is an integer averaging from about 10 to about 30.

16. A kit according to Claim 15 wherein the beverage composition is substantially free of one or more components selected from the group consisting of calcium and fluoride.

17. A kit according to Claim 16 wherein n is an integer averaging from about 13 to about 25.

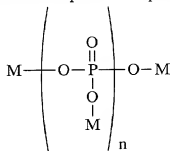
18. A kit according to Claim 17 wherein the beverage composition has a pH from about 2.7 to about 3.5.

19. A kit according to Claim 18 wherein the beverage composition comprises from about 0.1% to about 20% of the sweetener, by weight of the composition.

20. A kit according to Claim 19 wherein n is an integer averaging about 19 to about 25.

ABSTRACT OF THE DISCLOSURE

The present invention is directed to a method of treating dental erosion comprising orally administering to a mammal (preferably, a human) a beverage composition having a pH of less than about 5; wherein the beverage composition comprises a compound having the structure:



wherein n is an integer averaging from about 7 to about 100 and M, M', and M'' are each, independently, selected from the group consisting of sodium and potassium. The present invention is further directed to kits comprising the foregoing beverage composition and information that use of the beverage composition provides treatment against dental erosion.

DECLARATION COMBINED WITH POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled **Methods Of Using A Beverage Composition**:
the specification of which

(check one) ☒ is attached hereto.
☐ was filed on _____ as United States Application No. _____ or
PCT International Application Serial No. _____
and was amended on _____
(if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37 Code of Federal Regulations §1.56.

I hereby claim foreign priority benefits under Title 35 United States Code §119(a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate, or §365(a) of any PCT International application which designated at least one country other than the United States of America, listed below and have also identified below any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)

Priority Claimed

(Number)

(Country)

(Day/Month/Year Filed)

Yes

No

I hereby claim the benefit under Title 35, United States Code §119(e) of any United States provisional application(s) listed below.

Application Serial No.

Filing Date

Application Serial No.

Filing Date

I hereby claim the benefit under Title 35 United States Code §120 of any United States application(s), or §365(c) of any PCT International application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35 United States Code §112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37 Code of Federal Regulations §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

U.S. Parent Application Number	PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (If applicable)

As named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith:

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Atty Reg Number.

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